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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,567	09/19/2005	Peter Müllcjans	P70821US0	9658
136	7590	06/15/2007	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			HAND, MELANIE JO	
		ART UNIT		PAPER NUMBER
		3761		
		MAIL DATE	DELIVERY MODE	
		06/15/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,567	MULLEJANS ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 March 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 - 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection. The instant action is non-final in accordance with the agreement via telephone on February 14, 2007 noted by applicant.

Election/Restrictions

Newly submitted claim 18 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 18 is drawn to the embodiment of Figs. 4 and 6, whereas the invention originally claimed and examined is the embodiment of Figs. 1-3 and 5, setting forth a telescopic bellows formation for the bag liner.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 18 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claim 14 is objected to because of the following informalities: the newly added limitation "said inner bag liner being folded lengthwise so as to form a disc-like structure having a compact conformation" has previously been set forth in the body of claim 14 and so does not further limit the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness:

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolrich (U.S. Patent No. 5,423,782) in view of Brie (DE 19519069 (translation)).

With respect to **Claims 1,7,12**: Wolrich teaches an ostomy appliance comprising base plate 14 having a first hole and adhesive wafer 20 having a first surface to be attached to a wearer, a bag 12 releasably attached to said base plate, wherein the bag has a second hole for receiving waste and disposable inner bag liner 38 having a third hole 50 for receiving waste. The inner bag liner 38 is releasably attachable to base plate 14 in a first coupling area by first coupling means 46, and bag 12 is releasably attachable to base plate 14 by second coupling means 18. A first coupling means comprises flange 46 projecting from the rim of said third hole having a

first surface for releasable sealing against a second surface of base plate 14 facing away from the user.

Wolrich teaches that flange portion 46 allows bag liner 38 to be coupled to said first coupling means 46 in a fluid-tight relationship, but does not teach that flange 46 is an adhesive flange. It would be obvious to one of ordinary skill in the art to employ adhesive as opposed to the friction fit taught by Wolrich to couple the flange 46 to the first coupling means and thus to the base plate via adhesives with a reasonable expectation of success as adhesives are well-known in the art for their use in joining ostomy bags to securing members, thus also achieving a fluid-tight relationship.

Wolrich does not teach that second bag liner 38 is folded along a plurality of folding lines. Brie teaches an ostomy appliance having a first bag 4 and second bag liner 8 wherein bag liner 8 is folded lengthwise prior to use. The folds are configured to automatically unfold in response to receipt of wastes exiting a stoma such that said inner bag liner 8 is extended lengthwise within said receiving member or bag as the liner is filled. Brie teaches that the bag unfolds easily by blowing air into it, for example, thus the bag is necessarily configured to automatically unfold in response to receipt of waste exiting the stoma. Brie teaches that the folded arrangement of the bag 8 is preferred. Since the devices of Wolrich and Brie seek to solve a similar problem in the art, it would be obvious to one of ordinary skill in the art to modify the device of Wolrich by folding the inner bag liner as taught by Brie with a reasonable expectation of success. (Translation, pages 1-2)

With respect to **Claim 2**: Wolrich teaches that second coupling means 18 also employs a friction fit via ring and groove portions 34 and 36, and therefore does not teach that second coupling means is an adhesive flange. It would be obvious to one of ordinary skill in the art to employ

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adhesive as opposed to the friction fit taught by Wolrich to couple the second coupling means 18 to the base plate via adhesives with a reasonable expectation of success as hydrophobic adhesives are well-known in the art for their use in joining ostomy bags to securing members.

With respect to **Claim 3**: Bag 12 and bag liner 38 are joined together at third hole 50 and first coupling means 46 extends beyond the rim of third hole 50 whose diameter is equal to the inner diameter of second coupling means 18, therefore the outer diameter of first coupling means 46 is greater than the inner diameter of second coupling means 18.

With respect to **Claim 4**: Wolrich does not teach adhesives for the first and second coupling means and therefor does not teach relative peel strengths. Since the proper operation of the device depends upon the ability of the liner to be pulled out for disposal without rendering the reusable outer bag 12 unusable, i.e. the second coupling means must disengage before the first coupling means to allow the bag 12 to be pulled back for the liner 38 to be replaced and prevent waste from prematurely exiting the liner and staining the reusable bag, it would be obvious to one of ordinary skill in the art to employ adhesives as an alternate securing means to the friction fit taught by Wolrich, such that a relation exists between the peel strength of the first coupling means and second coupling means wherein the peel strength of the adhesive of the first means is stronger than the peel strength of the adhesive of the second means.

With respect to **Claim 5**: Second coupling means 18 is comprised of ring-shaped flange coupling 18 that mates with ring 34, therefore the second coupling means is in the form of one or more coupling rings. As can be seen in Fig. 1, the outer diameter of first coupling means 46 is less than the inner diameter of first coupling means 46.

With respect to **Claims 6,13**: Bag liner 38 taught by Wolrich is vapor permeable but liquid-impermeable, which allows intestinal gas to escape but is impermeable to liquids.

With respect to **Claim 8**: As can be seen in Fig. 6, the bag liner 38 taught by Wolrich is compacted lengthwise to form a disc-like structure having an outer diameter 44 that is less than the inner diameter of first coupling means 46.

With respect to **Claims 9,10**: Folding at the tapered edges 76,78 taught by Wolrich forms a bellows. The folding along the tapered edges 76,78 facilitates lengthwise compaction of the bag liner 38, the bellows is considered herein to be a telescopic bellows.

With respect to **Claim 14**: Wolrich teaches a method of applying to an ostomate an ostomy appliance comprising base plate 14 having a first hole and adhesive wafer 20 having a first surface to be attached to a wearer, a bag 12 releasably attached to said base plate, wherein the bag has a second hole for receiving waste and disposable inner bag liner 38 having a third hole 50 for receiving waste. As can be seen in Fig. 6, the bag liner 38 is capable of being compacted lengthwise to form a disc-like structure having a compact conformation and an outer diameter 44 that is less than the inner diameter of first coupling means 46. The inner bag liner 38 is releasably attachable to base plate 14 in a first coupling area by first coupling means 46, and bag 12 is releasably attachable to base plate 14 by second coupling means 18. First coupling means 46 comprises a flange projecting from the rim of said third hole having a first surface for releasable sealing against a second surface of base plate 14 facing away from the user.

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Wolrich teaches that flange portion 46 allows bag liner 38 to be coupled to first coupling means 18 in a fluid-tight relationship, but does not teach that flange 46 is an adhesive flange. It would be obvious to one of ordinary skill in the art to employ adhesive as opposed to the friction fit taught by Wolrich to couple the flange 46 to the first coupling means and thus to the base plate via adhesives with a reasonable expectation of success as hydrophobic adhesives are well-known in the art for their use in joining ostomy bags to securing members, thus also achieving a fluid-tight relationship.

Claims 11 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolrich (U.S. Patent No. 5,423,782) in view of Brie (DE 19519069 (translation)) as applied to claims 1-14 above, and further in view of Boehringer et al (U.S. Patent Application Publication No. 2004/0064132).

With respect to **claims 11,15,17**: The combined teaching of Wolrich and Brie does not teach that the step of securing said disc-like structure in said compact conformation is accomplished by placing a cover on a closed end of said inner bag liner. Boehringer teaches a device for treating a wound comprising a bellows-like enclosure that is configured for attachment to the skin wherein the compacted bellows configuration of the enclosure is maintained by a protective cover. The cover taught by Boehringer is a paper or film release liner, is readily removed from the enclosure and thus would be removed in use of said enclosure by automatic unfolding of said bag liner in response to receipt of waste exiting said stoma, ureter or catheter and entering an open end of said inner bag liner. Since the devices of the combined teaching of Wolrich and Brie and Boehringer seek to solve a similar problem in the art (i.e. provide a bellows type enclosure for receiving waste from a stoma or wound), it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Wolrich and Brie so as to be

maintained in a compact configuration by a cover as taught by Boehringer with a reasonable expectation of success. ('132, Figs. 1-2, ¶¶0014-0016)

With respect to **claim 16**: The cover taught by Boehringer (shown as item 20 in Fig. 1) is considered herein to be disposed on the closed end of said disc-like structure to retain said inner bag liner in a compact conformation prior to use. The basis for this argument is the presence of a suction drainage apparatus that is disposed on the opposite end of the structure, which necessarily would be the open end in order for the suction drainage apparatus to function. The motivation to combine the devices of Wolrich and Brie and Boehringer is stated *supra* with respect to claim 15.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

May 31, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

